Special 510(k) Premarket Notification – Sterile Packaging
Bundled Submission STRYKER SPINE Thoraco-lumbar Spinal Systems –
MANTIS®, MANTIS® Redux, Radius®, TRIO® & TRIO® +, TRIO® Trauma, XIA®,
XIA® 3, and XIA® 4.5

DEC 17 2013

510(k) Summary

Submitter:	Stryker Spine Building 59 / Route 17 South Allendale, New Jersey 07401
Contact Person	Ms. Soraya King Regulatory Affairs Specialist Phone: 201-760-8296 Fax: 201-962-4296 Email: soraya.king@stryker.com
Date Prepared	December 13, 2013
Trade/Device Name	1. MANTIS® & MANTIS® Redux Spinal Systems 2. Radius® Spinal System 3. TRIO® & TRIO + Spinal Fixation Systems 4. TRIO® TRAUMA Spinal System 5. XIA® Spinal Systems 6. XIA® 3 Spinal System 7. XIA® 4.5 Spinal System
Common Name	Spinal Fixation Appliances
Regulatory Class, Regulation Number, and Regulation Name	1. MANTIS® & MANTIS® Redux Spinal Systems • Class III • 21 CFR 888.3050: Spinal Interlaminal Fixation Orthosis • 21 CFR 888.3070: Pedicle Screw Spinal System 2. Radius® Spinal System • Class III • 21 CFR 888.3050: Spinal Interlaminal Fixation Orthosis • 21 CFR 888.3060: Spinal Intervertebral Body Fixation Orthosis • 21 CFR 888.3070: Pedicle Screw Spinal System 3. TRIO® & TRIO + Spinal Fixation Systems • Class III

	• CFR 888.3070: Pedicle Screw Spinal System 4. TRIO® TRAUMA Spinal Systems • Class III • 21 CFR 888.3070: Pedicle Screw Spinal System 5. XIA® Spinal Systems • Class III • 21 CFR 888.3050: Spinal Interlaminal Fixation Orthosis • 21 CFR 888.3060: Spinal Intervertebral Body Fixation Orthosis • 21 CFR 888.3070: Pedicle Screw Spinal System 6. XIA® 3 Spinal System • Class III • 21 CFR 888.3050: Spinal Interlaminal Fixation Orthosis • 21 CFR 888.3060: Spinal Intervertebral Body Fixation Orthosis • 21 CFR 888.3070: Pedicle Screw Spinal System 7. XIA® 4.5 Spinal System • Class III • 21 CFR 888.3050: Spinal Interlaminal Fixation Ortosis • 21 CFR 888.3060: Spinal Intervertebral Body Fixation Orthosis • 21 CFR 888.3070: Pedicle Screw Spinal System
Device Product Code	1. MANTIS® & MANTIS® Redux Spinal Systems • KWP, MNH, MNI, NKB 2. Radius® Spinal System • KWP, KWQ, MNH, MNI, NKB 3. TRIO® and TRIO + Spinal Fixation Systems • MNH, MNI, NKB 4. TRIO® Trauma Spinal System • MNH, MNI, NKB 5. XIA® Spinal Systems

	• KWP, KWQ, MNH, MNI, NKB 6. XIA® 3 Spinal System • KWP, KWQ, MNH, MNI, NKB, OSH 7. XIA® 4.5 Spinal System • KWP, KWQ, MNH, MNI, NKB, OSH
Predicate Devices	1. MANTIS® & MANTIS® Spinal Systems • K061813, K073151, K092631, and K102235 2. Radius® Spinal System • K062270, K07063, K082608, and K101144 3. TRIO® & TRIO + Spinal Fixation Systems • K052971, K062698, K070368, and K100737 4. TRIO® Trauma Spinal System • K103292 5. XIA® Spinal Systems • K982494, K013823, K031893, K043473, K052181, K060361, and K060979 6. XIA® 3 Spinal System • K071373, K083393, K091291, and K113666 7. XIA® 4.5 Spinal System • K050461, K060361, K060748, K060979, K092605, and K121342
Description of Device Modifications	The STRYKER Spine thoraco-lumbar spinal fixation systems, subject of this 510(k), are non-cervical, pedicle and non-pedicle fixation systems comprised of screws, rods, plates, hooks, connectors, washers and staples. The components are manufactured from either Titanium (Titanium Alloy and CP Titanium), Stainless Steel or Cobalt-Chromium-Molybdenum Alloy (Vitallium®). This Special 510(k) submission seeks clearance for sterile labeling of the listed STRYKER Spine thoraco-lumbar spinal fixation systems. All of the components of the subject devices will be sterilized by

	gamma radiation, a traditional sterilization method as per FDA guidance document, *Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA.*
Intended Use	<u>MANTIS® & MANTIS Redux Spinal Systems (K102235)</u> The MANTIS® Spinal System and MANIS® Redux Spinal System is intended for percutaneous, posterior, non-cervical pedicle and non-pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the following indications: • Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); • Spondylolisthesis; • Trauma (i.e. fracture or dislocation); • Spinal Stenosis; • Curvature (i.e. scoliosis, kyphosis, and/or lordosis); • Tumor; • Pseudoarthorisis; and • Failed Previous Fusion <u>Radius® Spinal System (K101144)</u> The Radius® Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the Radius® Spinal system is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);

	• Spondylolisthesis; • Trauma (i.e. fracture or dislocation); • Spinal Stenosis; • Curvature (i.e. scoliosis, kyphosis, and/or lordosis); • Tumor; • Pseudoarthorisis; • and Failed Pervious Fusion The Radius® Spinal System can also be linked to the XIA® Titanium Spinal System via the Ø5.5mm to Ø6.0mm Radius® rod-to-rod connector. <u>TRIO® Spinal Systems</u> ➢ *Stryker Spine TRIO® Plate System* (K070368) The Stryker Spine TRIO® Plate System is intended for posterior, noncervical (T10-S1) pedical and nonpedical fixation of the spine for the following indications: • Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); • Spondylolisthesis; • Trauma (i.e. fracture or dislocation); • Spinal Stenosis; • Curvature (i.e. scoliosis, kyphosis, and/or lordosis); • Tumor; • Pseudoarthorisis; • and Failed Pervious Fusion ➢ *Stryker Spine TRIO® Spinal Fixation System* (K070368) The Stryker Spine TRIO® Spinal Fixation System is intended for posterior, noncervical pedicle and non-pedicle fixation of the spine. The Stryker Spine TRIO® Spinal Fixation System is indicated for:

	• Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); • Spondylolisthesis; • Trauma (i.e. fracture or dislocation); • Spinal Stenosis; • Curvature (i.e. scoliosis, kyphosis, and/or lordosis); • Tumor; • Pseudoarthorisis; • and Failed Pervious Fusion The TRIO® Spinal Fixation Sytem is intended to be used in conjunction with the OSS Diapson Rods, Opus Spinal System Rods, and the Multi-Axis Cross Connectors. ➢ *Stryker Spine TRIO® + Spinal System* (K070368 & K100737) The Stryker Spine TRIO® Spinal System is intended for posterior, noncervical pedicle and nonpedicle fixation of the spine to provide immobilization and stabilization of spinal segements in skeletally mature patients as an adjunct to fusion for the following indications: • Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); • Spondylolisthesis; • Trauma (i.e. fracture or dislocation); • Spinal Stenosis; • Curvature (i.e. scoliosis, kyphosis, and/or lordosis); • Tumor; • Pseudoarthorisis; • and Failed Pervious Fusion The TRIO® + Spinal System is intended to be used in conjunction with the OSS/Diapason Rods or Opus Rods, XIA® Pre-bent Rods, and

	the Multi-Axis Cross Connectors. <u>TRIO® TRAUMA (K103292)</u> The Stryker Spine TRIO® TRAUMA Spinal System is intended for percutaneous, posterior, non-cervical pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the following indications: • Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); • Spondylolisthesis; • Trauma (i.e. fracture or dislocation); • Spinal Stenosis; • Curvature (i.e. scoliosis, kyphosis, and/or lordosis); • Tumor; • Pseudoarthorisis; • and Failed Pervious Fusion <u>XIA® Spinal Systems (K060361)</u> The XIA® Spinal System and XIA® 4.5 Spinal System are intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: • Degenerative Disc Disease (DDD) (Defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); • Spondylolisthesis; • Trauma (i.e., fracture or dislocation); • Spinal Stenosis; • Curvatures (i.e., Scoliosis, Kyphosis, and/or Lordosis); • Tumor;

	• Pseudoarthrosis and; • Failed previous fusion. The 6mm diameter rods from the DIAPASON® Spinal System and OPUS® Spinal System are intended to be used with the other components of the XIA® Titanium Spinal System. The Titanium Multi-Axial Cross Connector are intended to be used with the other components of the XIA® Titanium Spinal System <u>XIA® 3 Spinal System (K113666)</u> The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); • Spondylolisthesis; • Trauma (i.e. fracture or dislocation); • Spinal Stenosis; • Curvature (i.e. scoliosis, kyphosis, and/or lordosis); • Tumor; • Pseudoarthorisis; • and Failed Pervious Fusion The Ø5.5mm rods from the Stryker Spine Radius® Spinal System and the Ø6.0mm Vitallium Rods from the XIA® Spinal System are intended to be used with the other components of the XIA® 3 Spinal System. When used for posterior noncervical pedicle screw fixation in pediatric

	patients, the XIA® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. <u>XIA® 4.5 Spinal System (K121342)</u> The XIA® 4.5 Spinal System is intended for anterior/anteriolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: • Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); • Spondylolisthesis; • Trauma (i.e. fracture or dislocation); • Spinal Stenosis; • Curvature (i.e. scoliosis, kyphosis, and/or lordosis); • Tumor; • Pseudoarthorisis; • and Failed Pervious Fusion The Stryker Spine DIAPASON® Spinal System, OPUS® Spinal System and XIA® 4.5 Spinal System can be linked to the XIA® 4.5 Spinal System via the rod-to-rod connector when used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. Except for the staples, the XIA® 4.5 Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior noncervical pedicle screw fixation in pediatric patients. The XIA® 4.5 Spinal System for pediatric use in intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Special 510(k) Premarket Notification – Sterile Packaging

Bundled Submission STRYKER SPINE Thoraco-lumbar Spinal Systems –

MANTIS®, MANTIS® Redux, Radius®, TRIO® & TRIO® +, TRIO® Trauma, XIA®,

XIA® 3, and XIA® 4.5

Summary of the Technological Characteristics	The sterile packed implant components for the spinal fixation systems have the same technological characteristics as the non-sterile packed predicate devices. These characteristics include same design, technical requirements, materials of construction, and indications/ intended use. Design modifications were not incorporated to facilitate sterile packaging of the implants.
Conclusion	The subject devices that are intended to be sterile packed are safe and effective as the predicate non-sterile devices. The subject devices retain the same intended and indications for use, technological characteristics, and mode of operation as the predicate non-sterile devices. The accelerated aging data demonstrated that the sterilization process and sterile barrier packaging system are effective in maintaining sterility for the recommended 5 year shelf-life.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 17, 2013

Stryker Spine
Ms. Soraya King
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K133188
Trade/Device Name: MANTIS® and MANTIS® Redux Spinal Systems, Radius® Spinal System, TRIO® Spinal Fixation System, TRIO® Plate System, TRIO® + Spinal Fixation System, TRIO® TRAUMA Spinal System, XIA® Spinal Systems, XIA® 3 Spinal System, and XIA® 4.5 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB,OSH, MNH, MNI, KWP, KWQ
Dated: November 19, 2013
Received: November 20, 2013

Dear Ms. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use Statement

510(k) Number (if known): K133188

Device Name: MANTIS® and MANTIS® Redux Spinal Systems

Indications for Use:

The MANTIS® Spinal System and MANIS® Redux Spinal System is intended for percutaneous, posterior, non-cervical pedicle and non-pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal Stenosis;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis; and
- Failed Previous Fusion

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133188

Indications for Use Statement

510(k) Number (if known): K133188

Device Name: Radius® Spinal System

Indications for Use:

The Radius® Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the Radius® Spinal system is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal Stenosis;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis;
- and Failed Pervious Fusion

The Radius® Spinal System can also be linked to the XIA® Titanium Spinal System via the Ø5.5mm to Ø6.0mm Radius® rod-to-rod connector.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K133188

Indications for Use Statement

510(k) Number (if known): K133188

Device Name: TRIO® Spinal Fixation System

Indications for Use:

The Stryker Spine TRIO® Spinal Fixation System is intended for posterior, noncervical pedicle and non-pedicle fixation of the spine. The Stryker Spine TRIO® Spinal Fixation System is indicated for:

- Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal Stenosis;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis;
- and Failed Pervious Fusion

The TRIO® Spinal Fixation System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods, and the Multi-Axis Cross Connectors.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133188

Indications for Use Statement

510(k) Number (if known): K133188

Device Name: TRIO® Plate System

Indications for Use:

The Stryker Spine TRIO® Plate System is intended for posterior, noncervical (T10-S1) pedicle and nonpedicle fixation of the spine for the following indications:

- Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal Stenosis;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis;
- and Failed Pervious Fusion

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133188

Indications for Use Statement

510(k) Number (if known): K133188

Device Name: TRIO® + Spinal Fixation System

Indications for Use:

The Stryker Spine TRIO® Spinal System is intended for posterior, noncervical pedicle and nonpedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal Stenosis;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis;
- and Failed Pervious Fusion

The TRIO® + Spinal System is intended to be used in conjunction with the OSS/Diapason Rods or Opus Rods, XIA® Pre-bent Rods, and the Multi-Axis Cross Connectors.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133188

Indications for Use Statement

510(k) Number (if known): K133188

Device Name: TRIO® TRAUMA Spinal System

Indications for Use:

The Stryker Spine TRIO® TRAUMA Spinal System is intended for percutaneous, posterior, non-cervical pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal Stenosis;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis;
- and Failed Pervious Fusion

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133188

Indications for Use Statement

510(k) Number (if known): K133188

Device Name: XIA® Spinal Systems

Indications for Use:

The XIA® Spinal System and XIA® 4.5 Spinal System are intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications:

- Degenerative Disc Disease (DDD) (Defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal Stenosis;
- Curvatures (i.e., Scoliosis, Kyphosis, and/or Lordosis);
- Tumor;
- Pseudoarthrosis and;
- Failed previous fusion.

The 6mm diameter rods from the DIAPASON® Spinal System and OPUS® Spinal System are intended to be used with the other components of the XIA® Titanium Spinal System. The Titanium Multi-Axial Cross Connector are intended to be used with the other components of the XIA® Titanium Spinal System.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S 1

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133188

Indications for Use Statement

510(k) Number (if known): K133188

Device Name: XIA® 3 Spinal System

Indications for Use:

The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal Stenosis;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis;
- and Failed Pervious Fusion

The Ø5.5mm rods from the Stryker Spine Radius® Spinal System and the Ø6.0mm Vitallium Rods from the XIA® Spinal System are intended to be used with the other components of the XIA® 3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis.
The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft.
Pediatric pedicle screw fixation is limited to a posterior approach.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S 1

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133188

Indications for Use Statement

510(k) Number (if known): K133188

Device Name: XIA® 4.5 Spinal System

Indications for Use:

The XIA® 4.5 Spinal System is intended for anterior/anteriolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications:

- Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal Stenosis;
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthorisis;
- and Failed Pervious Fusion

The Stryker Spine DIAPASON® Spinal System, OPUS® Spinal System and XIA® 4.5 Spinal System can be linked to the XIA® 4.5 Spinal System via the rod-to-rod connector when used for the aforementioned indications in skeletally mature patients as an adjunct to fusion.

Except for the staples, the XIA® 4.5 Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior noncervical pedicle screw fixation in pediatric patients. The XIA® 4.5 Spinal System for pediatric use in intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133188